UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,872	06/29/1998	SYDNEY M PUGH	3477/116	6664

62644 7590 08/07/2009

MEDTRONIC
Attn: Noreen Johnson - IP Legal Department
2600 Sofamor Danek Drive
MEMPHIS, TN 38132

EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/029,872	PUGH ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,12,23,26,38,47-53 and 55-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,12,23,26,38,47-53 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/2009, 11/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 12, 23, 38, 47, and 57 are rejected under 35 U.S.C. 102(b) as anticipated by Ruys (article entitled "Silicon-doped Hydroxyapatite") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxyapatite and silicon which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). Due to the vague language used in the specification pertaining to the basic and novel characteristics, the language "consisting essentially of" has been interpreted as comprising; see MPEP 2111.03 that is incorporated herein by reference. Although not preferred, it was made into a material that was close to a ratio of 50:50 that is within the claimed range; see page 77, lines 15-17. The result of Ruys' process is a bulk material. The concentration of silicon results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50

mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

Furthermore, since the material of Ruys is the same as that claimed, it would inherently be insoluble in physiological fluids and have the same resorbability and *in vivo* response as claimed because it is the same material as that claimed alpha-tricalcium phosphate; see page 72.

> *The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

Alternatively, one may not consider Ruys as meeting the claim language because the disclosure of the amounts of components is not analyzed in detail, and Ruys prefers low dopant levels to avoid tricalcium phosphate (i.e. TCP) and the associated biodegradability. However, since low dopant levels are only preferred and the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been at least obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

Claim 26 is rejected under 35 U.S.C. 103(a) as obvious over Ruys (article entitled “Silicon-doped Hydroxyapatite”) alone.

With regard to claim 26, Ruys fails to disclose the particle size as claimed even though it was disclosed as being crushed and pelletized; see page 76. However, since it was known, in the art, to crush and pelletize the same material as claimed, it is the Examiner's position that the mere selection of a particle size would have been considered *prima facie* obvious to an ordinary artisan because it has not shown to provide some advantage, solve some stated problem or used for some particular purpose, the Examiner takes the position that it would have been considered *prima facie* obvious to use the claimed particle size with the Ruys composition; see MPEP 2144.04.

> In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 48 to 53 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys discloses materials where the TCP content is slightly greater than the hydroxyapatite content; see page 77, lines 15-17. However, since low dopant levels are only preferred and the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been clearly obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

Claims 1, 12, 38, 47-53 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (WO 94/26872) in view of Ruys (article entitled "Silicon-doped

Hydroxyapatite"). Davies meets the claim language where alpha tricalcium phosphate is formed from Hydroxyapatite (HA) by sintering at temperatures from 800 ^{0}C to 1100 ^{0}C; see page 7, line 24 to page 8, line 27 and page 27, line 11 et seq. The stabilizing entity as claimed is silicon from the quartz substrate because quartz is SiO_2. Since the ratio of tricalcium phosphate to hydroxyapatite can be up to 90:10, the claimed ranges are considered clearly met. However, Davies fails to disclose making the composition into the form of a powder, granules, or a bulk material as now claimed. Ruys, however, teaches that it was known to make silicon doped HA into bulk materials, granules, or powders; see the previously cited portions thereof. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to an ordinary artisan to make the composition of Davies into bulk material, granular, or powder form so a test of actual *in vivo* bone substitution can performed as taught by Ruys; see the abstract thereof.

With regard to claim 12, the material produced by Davies is inherently insoluble to the extent claimed because it is the same material as that claimed.

Response to Arguments

Applicant's arguments filed May 20, 2009 have been considered but they are not fully persuasive.

With regard to the Section 112 rejections, the arguments presented were persuasive, and thus, the rejections have been withdrawn. In particular, page 12 of the specification suggests that ratios higher than 90:10 were contemplated and enabled by the sintering temperature of 1,200 ^{0}C.

With regard to the prior art rejections utilizing Ruys, the Examiner reiterates that Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxyapatite and silicon which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). Due to the vague language used in the specification pertaining to the basic and novel characteristics, the language "consisting essentially of" has been interpreted as comprising; see MPEP 2111.03 that is incorporated herein by reference. Although not preferred, it was made into a material that was close to a ratio of 50:50 that is within the claimed range; see page 77, lines 15-17. The result of Ruys' process is a bulk material. The concentration of silicon results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

Furthermore, since silicon doping ratio can be 0 to 50 and the majority of the time below 2, the Examiner asserts that low doping levels were clearly contemplated and at least obvious in view of Ruys; see page 76 under the heading "Silicon Additions."

It is noted that "consisting essentially of" does not preclude other calcium phosphate phases (see page 9, line 24 to page 10, line 20) or other contaminants (see page 12, lines 9-19). Furthermore, the basic and novel characteristic is that the alpha tricalcium phosphate not be soluble in physiological fluids as provided by the stabilization. In particular, page 12 of the present specification states that the contaminant "**preferably** does not affect the composition and morphology of the stabilized composition in any manner which will affect the support of bone cell activity

thereon." (emphasis added) This sort of vague language suggests that the amount of bone cell activity is merely a preference. For this reason, the claim language "consisting essentially of" has been interpreted as having the same meaning as "comprising"; see MPEP 2111.03.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774